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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BLECK, CAROLYN M

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/476,415	SANDBERG, DALE
Examiner	Art Unit	
Carolyn M Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 22 October 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 21-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 21-40 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment filed 22 October 2002.

Claims 1-20 have been cancelled. Claims 21-40 are newly added.

***Drawings***

2. The objections of the drawings are hereby withdrawn due to the amendment filed 22 October 2002.

***Specification***

3. The objections of the abstract are hereby withdrawn due to the amendment filed 22 October 2002.

4. The amendment filed 22 October 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added recitation of "a dynamically customizable form" appears to constitute new matter. In particular, Applicant does not point to, nor was the Examiner able to find, any support for generating the "dynamically customizable form". As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office action.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The specification is objected to under 35 U.S.C. § 112, first paragraph, because the specification, as originally filed, does not provide support for the invention as is now claimed for the reasons given in section 4 above.

***Claim Objections***

7. Claims 36-37 are objected to because of the following informalities: it appears the phrases "wherein the one or more healthcare procedures and the one or more healthcare procedures", claim 36 lines 1-2, and "wherein the one or more healthcare diagnoses and the one or more healthcare diagnoses", claim 37 lines 1-2, are grammatically incorrect . Appropriate correction is requested.

***Claim Rejections - 35 USC § 112***

8. Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and for the reasons set forth in the objection to the specification above.

9. Independent claims 21 and 33 recite limitations that are new matter, as discussed above.

10. Claims 22-32 and 34-40 incorporate the deficiencies of independent claims 21 and 33, through dependency, and are also rejected.

**NOTE:** For purposes of applying prior art and to the extent that the Examiner understands the specification, in particular page 13 line 5 to page 18 line 24, "a dynamically customizable form" is assumed to be a visit form established and defined by the user selecting a "Visit Form Definition" operation (see page 13 lines 22-23 of the specification) where the user is able to define the form such as procedure and diagnosis column width and sequence based on the user's personal taste and functional arrangement of the actual visit form (see page 15 lines 7-10).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**NOTE:** The following rejections assume that the subject matter added in 22 October 2002 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in sections 4-9 above in the next communication sent in response to the present Office Action.

12. Claims 21-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) in view of Feldon et al. (5,732,221).

(A) As per claim 21- 22, 24-25, and 30-32, Evans discloses a medical records method and system for storage and retrieval of dynamic electronic medical records in a computer environment, such as a local or wide area network including portable computers (col. 1 lines 5-10), wherein patient data, such as patient complaints, lab orders, medications, diagnoses, and procedures, are captured at the point of care of a

patient in real-time, such as during an examination, using a graphical user interface having touch screens in a point of care system (Abstract; lines 1-5; col. 2 lines 20-64, col. 5 lines 29-55, and col. 5 lines 8-10), comprising:

(a) entering patient data electronically, wherein the health care provider clicks on a scroll down button to select a form from a list of available forms for entering patient data, wherein a new forms box is activated, wherein the provider then clicks on a new form buttons, and wherein a new form window is then displayed, wherein the health care provider then fills out the form using an input device, such as a keyboard, mouse, or an electronic pen, and wherein the provider then exits the form using the File Menu and the patient record is filed in the patient data repository for future reference

(Abstract, lines 1-2; Fig. 5-6, col. 5 lines 28-55, and col. 6 line 55 to col. 7 line 5); and

(b) wherein the patient data entered or selected includes diagnoses and procedures (Fig. 20-21 and col. 6 lines 9-36), including ICD9 diagnosis codes and CPT procedure codes (Fig. 1 and 14, col. 9 lines 4-13, and col. 11 lines 36-64).

Evans fails to expressly disclose generating a dynamically customizable form, including selecting procedures and diagnoses for inclusion within the form. However, Evans discloses entering patient data through an electronic form as discussed above system (Abstract; lines 1-5; col. 2 lines 20-64, col. 5 lines 29-55, and col. 5 lines 8-10).

Feldon discloses entering a patient's demographic information, medical history, prescribed medication and other relevant information for a patient, including information a physician documents during the exam using exam descriptors, into data entry forms, wherein a user is able to customize these data entry forms by editing existing forms or

by redesigning completely new forms, wherein the form is able to be saved (col. 4 lines 13-63, col. 8 lines 62-67, and col. 9 lines 15-65, col. 11 lines 1-58, and col. 12 lines 1-9).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Feldon within the method of Evans with the motivation of allowing forms to be generated based on the user's needs and customized for the particular task at hand (Feldon; col. 4 lines 52-54) and transforming a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record (Evans; col. 2 lines 34-40).

(B) As per claim 23, Evans discloses a data interface permitting communication with external sources to obtain patient data and to transfer patient information to external health care providers, such as demographic data, laboratory test results, x-ray images, ICD9 diagnosis codes and CPT procedure codes, prescriptions for medications (col. 9 lines 1-14). The remainder of claim 23 repeats the same limitations as claim 21, and is therefore rejected for the same reasons given for claim 21, and incorporated herein. It is noted that the step of transferring patient information, including ICD9 diagnosis codes and CPT procedure codes, to external health care providers (col. 9 lines 1-14) is considered to be a form of "one or more other healthcare procedures or diagnoses used by another healthcare provider of a healthcare facility" as recited in claim 23.

(C) As per claim 26, Feldon discloses customizing data entry forms for a physician, for example for an examination of the eye by defining common types of eye exams (col. 1

line 20 to col. 2 line 12 and col. 4 lines 30-45). The remainder of claim 26 repeats the same limitations as claim 21, and is therefore rejected for the same reasons given for claim 21, and incorporated herein. The motivation for combining Feldon within Evans is given above in claim 21, and is incorporated herein.

(D) As per claim 27-29, Evans discloses entering and updating a patient record using a form, wherein the patient record includes insurance information, ICD9 diagnosis codes and CPT procedure codes, wherein upon entering and updating information, the electronic medical record system filed the patient's record in real-time in the patient data repository (Abstract, lines 1-2; Fig. 2-3, 5-6, and 14, col. 5 lines 1-27, col. 6 line 55 to col. 7 line 5, col. 9 lines 1-14).

It is noted that Evan's discloses recording insurance information as well as diagnosis and procedure codes within a patient record as discussed above (Abstract, lines 1-2; Fig. 2-3, 5-6, and 14, col. 5 lines 1-27, col. 6 line 55 to col. 7 line 5, col. 9 lines 1-14). As this information is most frequently used for billing purposes (i.e., billing insurance companies), it is respectfully submitted that this information within the patient record is a form of a "billing record. Furthermore, as per the recitation of "the billing record corresponding to standards in the industry," it is noted that ICD9 codes and CPT codes are widely accepted codes used to report and index medical records and are considered to be the standard codes set for reporting health care services in electronic data transactions.

(E) Claims 33-40 differ from method claims 21-32 by reciting hardware elements, namely, a computer readable medium and computer program code which is executable. As per these elements, Evans discloses:

- (a) a multi-processor personal computer having 20 GB of storage capacity (col. 12 line 66 to col. 13 line 30); and
- (b) applications running under Microsoft ® Windows ™ to access data from a variety of data sources (col. 13 line 57 to col. 14 line 25).

The remainder of claims 33-40 repeat the same limitations as claims 21-32, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

#### ***Response to Arguments***

13. Applicant's arguments with respect to claims 21-40 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

17. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**Or faxed to:**

(703) 305-7687 [Official communications; including After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

*CB*

CB

December 16, 2002

*Dinh X. Nguyen*  
DINH X. NGUYEN  
PRIMARY EXAMINER

## **Recent Statutory Changes to 35 U.S.C. § 102(e)**

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

**A person shall be entitled to a patent unless –**

**(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.**

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

**A person shall be entitled to a patent unless –**

**(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.**

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at [www.uspto.gov](http://www.uspto.gov) or call the Office of Patent Legal Administration at (703) 305-1622.